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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/402,450	09/01/1989	GEORGE J. MURAKAWA		8131

6449 7590 10/04/2006

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EXAMINER

MILLER, MARINA I

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

07/402,450

Applicant(s)

MURAKAWA ET AL.

Examiner

Marina Miller

Art Unit

1631

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 18 September 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 114-234.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
10/2/06

Continuation of 3. NOTE: filed amendments, i.e., a newly added limitation ""wherein the reference RNA sequence and the selected target viral RNA sequence are of similar length and capable of being amplified by the same oligonucleotides" raises a new issue under 35 USC 102, 103, 112, first and second paragraphs.

Continuation of 11. does NOT place the application in condition for allowance because: As the amendment is not entered, applicants' arguments with regard to the proposed amendments are not persuasive.

Applicants' arguments regarding the rejection under 35 USC 102(a) over Murakawa are based on the assertion that Murakawa is not a prior art against the instant claims. For the reasons set forth in the final office action mailed 3/16/2006, the examiner maintains that priority applications '045 and '959 do not provide support for the instant claims and priority for claims 114-234 is granted only to the filing date of the instant application filed 9/1/198.

With respect to the arguments NOT directed to the amendment.

Applicants further argue regarding the rejection under 35 USC 103, that Chelly does not disclose adding a known amount of reference RNA to a sample and the absolute quantification of a target. Applicants argue that Chelly only discloses the relative amount based on a ratio of a target to a standard, wherein the instant claims recite the absolute quantification. Applicants also argue that there is no motivation to combine the references.

In response to the argument, applicants are reminded that the rejection is made under 35 U.S.C. 103(a) over a combination of references. Murakawa discloses adding a known amount of a reference RNA to a sample. Specifically, 50 ng of PGM92+21 is added to a viral RNA prepared from blood and amplified for 15 cycles (fig. 8). Also, an equimolar amount of RNA from PGM92+21 (reference) was added to pGM92 (a sample comprising a selected target viral RNA) (fig. 7 and p. 292). Although Murakawa does not teach measuring the amount of amplified products, and quantifying a target RNA, Chelly does teach these limitations.

Chelly discloses measuring amplification products and quantifying the starting amount of a target RNA using a ratio of the amount of a standard before and after the amplification and the amount of a target after the amplification, similar to the "determination" step recited in instant claim 114, step (v). Specifically, Chelly discloses measuring the amount of amplified product by using, for example, labeled primers (p. 859), quantifying the starting material (p. 859), and a simple mathematical equation for calculating the initial amount of RNA (a ratio of the amount before and after amplification of a reference RNA) (p. 859 and 860, fig. 3).

It is noted that the instant claims do use "ratios", i.e., the initial amount of a target IS determined from the amount of a reference RNA before and after the amplification and the amount of a target after the amplification (i.e., a ratio).

Motivation to combine the references was provided in the final office action mailed 3/16/2006.

Thus, the examiner maintains that Murakawa and Chelly do disclose adding a known amount of a target and determining the amount of the target before the amplification from the amount of a reference before and after the amplification and the amount of the target after the amplification.